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June 12, 2015

Stephanie Vaughn
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U.S. Environmental Protection Agency, Region 2
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Via Electronic Delivery

Re: Lower Passaic River Study Area (LPRSA) Draft Baseline Human Health Risk Assessment (BHHRA) – USEPA Region 2 Comments – May 2007 Administrative Agreement and Order on Consent for Remedial Investigation/Feasibility Study – CERCLA Docket No. 02-2007-2009 (AOC)

Dear Ms. Vaughn:

This will acknowledge and respond to, on a strictly preliminary basis, the USEPA Region 2 (Region 2) comments sent to the Cooperating Parties Group (CPG) on June 5, 2015 on the draft 17-mile Baseline Human Health Risk Assessment (BHHRA) that the CPG submitted to Region 2 on June 6, 2014. The CPG believes the draft BHHRA should have been accepted by Region 2, pursuant to paragraph 44 (a or b) of the AOC. Further, it is troubling that it took Region 2 one full year to provide comments on a report that fully complies with project directives and agreements (including results of the 2012 dispute resolution), as well as USEPA national guidance and policy. The CPG is continuing to evaluate the extensive list of comments Region 2 provided and reserves its right to respond in detail in due course.

First, the CPG disputes Region 2's implication in the June 5 cover e-mail that the 17-mile BHHRA is deficient. This implication appears all the more unfounded and without merit when the actual risk estimates are compared between the Region's 8-mile Focused Feasibility Study (FFS) HHRA (Appendix D) and the 17-mile BHHRA. Most notably, the Region fails to acknowledge in any of its 220 comments that the CPG's risk estimates for the mixed fish and crab consumption pathways are nearly the same as those estimated by Region 2 in its 8-mile FFS, as shown below for cancer risk.

Mixed fish diet including carp	R2 8-mile FFS HHRA	CPG 17-mile BHHRA
Adult Angler	4E-03	3E-03
Child Angler	1E-03	1E-03
Combined Adult/Child	5E-03	4E-03

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Crab muscle & hepatopancreas	R2 8-mile FFS HHRA	CPG 17-mile BHHRA
Adult Angler	1E-03	9E-04
Child Anger	5E-04	4E-04
Combined Adult/Child	1.5E-03	1.3E-03

The differences between these two sets of risk estimates are not substantive or meaningful.

Second, Region 2 directs that important information contained in the BHHRA be eliminated because it does not comport with the Region's interpretation of what constitutes "reasonable maximum exposure" or it acknowledges conservatism in the risk assessment process. However, the Region's interpretation is extremely narrow, inflexible, and not supported by USEPA guidance.

Third, the Region's BHHRA comments unfairly and inaccurately impugn the CPG's work, misrepresent the report, and make statements that are not supported. The following examples highlight some of the major discrepancies with the Region's June 5 BHHRA comments:

- General Comment 4, which states that a mixed diet without carp should be removed from the report entirely or presented only in the uncertainty section, because excluding a species that is known to be kept by some anglers and have elevated COPC levels does not represent an RME scenario. A similar statement is made regarding crab, and that discussion of a muscle-only diet should not be included alongside the RME scenario of crab muscle and hepatopancreas consumption. General Comment 4 further asserts that "in general, one RME scenario should be presented for each exposure pathway".

The CPG is not aware of USEPA guidance providing that BHHRA's should have only one RME scenario per exposure pathway. As stated in the draft BHHRA (Section 4.4.5.3), it is because not all LPRSA anglers consume carp and this species has been shown to have some of the highest concentrations of COPCs, that the RME risks are presented for a mixed fish diet with and without carp. The CPG maintains this approach is consistent with USEPA guidance, actually provides clarity and transparency, and is consistent with both the Region 2-approved Problem Formulation Document and the 2009 Tissue QAPP, which did not identify carp as one of the four target species. Providing multiple RME scenarios for both crab and fish provides both the risk manager and the public a full and more complete understanding of the current potential risks associated with the 17-mile LPRSA.

- Specific Comment 64, which requests changes and additions to text describing the Tierra creel/angler survey. After refusing to allow the results of this site-specific survey be used to inform the BHHRA, during the February 2012 dispute resolution the Region directed specific language be used to describe Tierra's CAS, which the CPG has followed in the BHHRA. Now, the Region is requesting further changes to the language, including adding references to the Region's Letters to the Editor on Tierra's published risk assessment of the Lower Passaic River. The CPG does not

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believe such references are necessary or relevant to the 17-mile BHHRA, but as importantly, the CPG should not be asked to reconsider language that was previously stipulated by the Region.

- General Comment 8, which states, *"Throughout the document the terms Chemicals of Potential Concern (COPC) and Chemicals of Concern (COC) are used interchangeably"*. This is not the case. The term COC is first introduced in Section 6 (Risk Characterization) and discussed appropriately in Section 6.4, COC Identification, where the COPCs causing exceedance of risk benchmarks are identified. The report is clear in distinguishing between COPCs and COCs, and the Region's comment is not accurate.
- General Comment 10, which states that the text needs to clarify that the basis for risk management decisions is the RME, and that *"the text suggests decisions may be based on the CTE"*. The discussion regarding RME and CTE scenarios is entirely consistent with language provided by Region 2 in its comments on the draft RARC (see Comment 98 of EPA's July 11, 2011 comments). As directed by Region 2 in its July 11, 2011 comments, this language was included in the RARC and has been included in the applicable section of the BHHRA (Section 4.3), including the specific RAGS Part A Chapter 6 quote referenced in General Comment 10. In addition, General Comment 10 states that the text in several places *"appears to concentrate on population risks and hazards"*. The CPG requests the Region provide examples of where in the text population risks and hazards are discussed, as a search of the 17-mile BHHRA for the term *"population risk"* found none.
- General Comment 11, which states, *"Throughout the document, the term "more realistic" is used to discuss CTE exposures or alternative exposure factors*. This is simply not true. The only places in the document where *"more realistic"* is used to describe alternative exposure factors is in the Uncertainty Evaluation (Section 7), which is an appropriate place for discussions of alternative assumptions, as well as matters of scientific debate. Nowhere in the Exposure Assessment (Section 4) are CTE exposures referred to as *"more realistic"*. In Section 7.2.1 of the uncertainty evaluation, *"more realistic"* is used in reference to an adult body weight of 80 kilograms, swimming exposure times less than 2.6 hours, fish consumption rates less than 34.6 g/day and fraction ingested values of less than 1, and cooking loss values other than zero. This is hardly *"throughout the document"* and Region 2's assertion of such is incorrect and misleading.
- General Comment 14 and Specific Comments 29, 64, 68, 69, 71, 123, which relate to changes to exposure assumption values and/or references used in the BHHRA. The CPG used the exposure assumption values and references that Region 2 directed for use in the BHHRA. While the Region notes that *"we do not expect changes in these values to significantly affect the overall calculations of risk for the site"*, it is of great concern to the CPG that Region 2 treats the exposure parameters as a moving target.
- Specific Comment 46, which states that EPA would like to perform a thorough review of the data used in the draft BHHRA, and requests more details and the

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Excel tables showing the data used. Appendix A of the BHHRA provides a full cross-tab of the data used by medium, and the tables and figures in Section 3 provide details on the samples and their locations in the river. CPG must question the efficacy of the Region's review and oversight if it is still reviewing the data used in the draft BHHRA, after having all of the necessary information to perform a review for a full year. In fact, the list of 143 accessible sediment samples was sent to Region 2 in February of 2014, and again in March 2014, after a meeting with the Region and the Partner Agencies where the data sets used in the BHHRA were discussed. Specific Comment 127 (d & e) requests that alternative fish consumption rates, such as the national 95th percentile per capita rate, the rate used by EPA to derive water quality criteria, and one fish meal per month, be removed from the discussion of uncertainty in fish ingestion parameters, because they do not represent the RME individual. However, presenting a range of fish consumption rates (all of which are within the CTE and RME range identified by Region 2 for the LPRSA) and their influence on risk is what an uncertainty analysis is intended to do, as it provides context and information that is useful to risk managers and the public. Further, guidance does not prescribe such narrow boundaries for evaluating parameter uncertainty, as illustrated in Exhibit 8-5 of RAGS guidance.

- Specific Comment 209 (BERA Comment 6) is explicitly incomplete and refers to information or materials on background that Region 2 has failed to provide to the CPG since the May 1, 2015 BERA comments were released, leaving the CPG in a position of being directed to prepare expensive and time consuming responses and revisions without knowing what revisions are required or will be acceptable.

Region 2 and the CPG have scheduled a call on June 15 to discuss the BHHRA comments, as well as the status of overdue information promised by Region 2 on the BERA comments. The CPG will continue to identify and elaborate its concerns in an attempt to resolve the issues expeditiously and informally. However, the Region's continued delay in providing Comment 209 (BERA Comment 6) information promised since May 1 and resolution of the comments discussed in the CPG's May 29 letter will prevent the CPG from complying with Region 2's directive to revise and resubmit the revised BHHRA within 60 days. Thus, the CPG reserves its right to take other steps, such as invoking dispute resolution under Section XV of the AOC to protect its interests, after Region 2 provides all of its comments on the BHHRA. However, to the extent that Region 2 deems its comments complete and not preliminary, then this letter constitutes the invocation of dispute resolution regarding the same pursuant to Section XV of the AOC.

The CPG requests that Region 2 include this letter into the Administrative Record for the 17-mile LPRSA operable unit of the Diamond Alkali Superfund Site.

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Please contact Bill Potter or me with any questions or comments.

Very truly yours,
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